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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,925	04/15/2004	Kenneth T. Heruth	1023-350US01	1024

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EXAMINER

MALLARI, PATRICIA C

ART UNIT	PAPER NUMBER
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3735

NOTIFICATION DATE	DELIVERY MODE
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05/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@ssiplaw.com

Office Action Summary	Application No. 10/826,925	Applicant(s) HERUTH ET AL.	
	Examiner PATRICIA C. MALLARI	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-56 and 83-99 is/are pending in the application.
- 4a) Of the above claim(s) 44 and 99 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 48-56 and 83-99 is/are allowed.
- 6) ☒ Claim(s) 24, 38 and 39 is/are rejected.
- 7) ☒ Claim(s) 25-43 and 45-47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/16/08, 9/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is a non-final Office action. The double patenting rejections set forth below were not necessitated by the amendments to the claims.

Information Disclosure Statement

The information disclosure statement filed 1/16/08 has been considered.

The applicants should note that the large number of references in the submitted information disclosure statements have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b).** Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated

by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 24, 38, and 39 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 55 and 56 of U.S. Patent No. 7,366,572 (herein referred to as patent '572) or claims 71 and 72, respectively of the corresponding US Patent Application No. 10/825953, in view of US Patent Application Publication No. 2005/0076908 to Lee et al. Regarding claim 24, claim 55 of patent '572 recites a therapy module, wherein such a therapy module is clearly a medical device and wherein the device delivers therapy to a patient. The claim further recites a memory and a processor, wherein the processor determines a value of a metric

indicative of sleep quality based on values of at least one physiological parameter received from a sensor. The processor further associates the sleep quality metric with the therapy parameter set and stores the sleep quality metric value in association with the therapy set within the memory, such that the memory, therefore, receives the sleep quality metric value and an indication of the therapy parameter set associate with the value. Claim 55 of patent '572 lacks the medical device monitoring the physiological parameter and the parameter values being determined during delivery of the therapy by the medical device.

However, Lee discloses a medical system comprising a medical device that delivers therapy to a patient, wherein the medical device also monitors at least one physiological parameter of a patient based on a signal from a sensor determined during delivery of the therapy by the medical device according to a therapy set and wherein the physiological parameter is used to determine the value of a metric indicative of sleep quality, wherein the sleep quality metric value is used to assess the efficacy of the current therapy (see entire document, especially fig. 1D; paragraphs 40, 50-57, 80-82, 87, 156, 172-174 of Lee). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the medical device and sensor of Lee as that of claim 55 of patent '572, since claim 55 of patent '572 recites using a therapy module to deliver a therapy to a patient and at least one sensor from which a signal for at least one physiological parameter of a patient is received and Lee discloses such a therapy module and sensor, in order to allow the therapy to be adjusted to better suit the patient's needs.

Regarding claims 38 and 39, claim 55 of patent '572, as modified, recites the processor determining a plurality of values of the sleep quality metric over time, each of the values determined based on values of the at least one physiological parameter, wherein according to the combination, as described above, each value of the parameter is determined during delivery of the therapy according to the current parameter set. Claim 55 of patent '572, as modified further recites the current therapy parameter set being at least one of a plurality of therapy parameter sets and associating each of the determined values of the metric with the at least one of the plurality of therapy sets. For each of the plurality of therapy parameter sets, the processor further determines a representative value of the sleep quality metric based on values of the sleep quality metric associated with the therapy parameter set.

With further regard to claim 39, claim 56 of patent '572 recites the representative value for each therapy parameter set comprising one of a mean value or a median value.

Claims 24 and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 19 of copending Application No. 11/081155 (herein referred to as application '155) in view of US Patent Application Publication No. 2005/0076908 to Lee et al. Regarding claim 24, claim 19 of application '155 depends upon claim 11 and recites a therapy module, wherein such a therapy module is clearly a medical device and wherein the device delivers therapy to a patient (see claim 11 of application '155). The claim further recites a memory and a

processor, wherein the processor determines a value of a metric indicative of sleep quality based on values of at least one physiological parameter received from a sensor (see claim 11 of application '155). The processor further associates the sleep quality metric with the therapy parameter set and stores the sleep quality metric value in association with the therapy set within the memory, such that the memory, therefore, receives the sleep quality metric value and an indication of the therapy parameter set associate with the value (see claim 19 of application '155). Claim 19 of application '155 lacks the medical device monitoring the physiological parameter and the parameter values being determined during delivery of the therapy by the medical device.

However, Lee discloses a medical system comprising a medical device that delivers therapy to a patient, wherein the medical device also monitors at least one physiological parameter of a patient based on a signal from a sensor determined during delivery of the therapy by the medical device according to a therapy set and wherein the physiological parameter is used to determine the value of a metric indicative of sleep quality, wherein the sleep quality metric value is used to assess the efficacy of the current therapy (see entire document, especially fig. 1D; paragraphs 40, 50-57, 80-82, 87, 156, 172-174 of Lee). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the medical device and sensor of Lee as that of claim 19 of application '199, since claim 19 of application '199 recites using a therapy module to deliver a therapy to a patient and at least one sensor from which a signal for at least one physiological parameter of a patient is received and Lee discloses

such a therapy module and sensor, in order to allow the therapy to be adjusted to better suit the patient's needs.

Regarding claim 38, claim 19 of application '155, as modified, recites the processor determining a plurality of values of the sleep quality metric over time, each of the values determined based on values of the at least one physiological parameter, wherein according to the combination, as described above, each value of the parameter is determined during delivery of the therapy according to the current parameter set. Claim 19 of application '155, as modified, further recites the current therapy parameter set being at least one of a plurality of therapy parameter sets and associating each of the determined values of the metric with the at least one of the plurality of therapy sets. For each of the plurality of therapy parameter sets, the processor further determines a representative value of the sleep quality metric based on values of the sleep quality metric associated with the therapy parameter set.

This is a provisional obviousness-type double patenting rejection.

Claims 24 and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 20 of copending Application No. 11/691430 (herein referred to as application '430) in view of US Patent Application Publication No. 2005/0076908 to Lee et al. Regarding claim 24, claim 20 of application '430 depends upon claim 11 and recites a therapy module, wherein such a therapy module is clearly a medical device and wherein the device delivers therapy to a patient (see claim 11 of application '430). The claim further recites a memory and a

processor, wherein the processor determines a value of a metric indicative of sleep quality based on values of at least one physiological parameter received from a sensor (see claim 11 of application '430). The processor further associates the sleep quality metric with the therapy parameter set and stores the sleep quality metric value in association with the therapy set within the memory, such that the memory, therefore, receives the sleep quality metric value and an indication of the therapy parameter set associate with the value (see claim 20 of application '430). Claim 20 of application '430 lacks the medical device monitoring the physiological parameter and the parameter values being determined during delivery of the therapy by the medical device.

However, Lee discloses a medical system comprising a medical device that delivers therapy to a patient, wherein the medical device also monitors at least one physiological parameter of a patient based on a signal from a sensor determined during delivery of the therapy by the medical device according to a therapy set and wherein the physiological parameter is used to determine the value of a metric indicative of sleep quality, wherein the sleep quality metric value is used to assess the efficacy of the current therapy (see entire document, especially fig. 1D; paragraphs 40, 50-57, 80-82, 87, 156, 172-174 of Lee). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to use the medical device and sensor of Lee as that of claim 20 of application '430, since claim 20 of application '430 recites using a therapy module to deliver a therapy to a patient and at least one sensor from which a signal for at least one physiological parameter of a patient is received and Lee discloses

such a therapy module and sensor, in order to allow the therapy to be adjusted to better suit the patient's needs.

Regarding claim 38, claim 20 of application '430, as modified, recites the processor determining a plurality of values of the sleep quality metric over time, each of the values determined based on values of the at least one physiological parameter, wherein according to the combination, as described above, each value of the parameter is determined during delivery of the therapy according to the current parameter set. Claim 20 of application '430, as modified, further recites the current therapy parameter set being at least one of a plurality of therapy parameter sets and associating each of the determined values of the metric with the at least one of the plurality of therapy sets. For each of the plurality of therapy parameter sets, the processor further determines a representative value of the sleep quality metric based on values of the sleep quality metric associated with the therapy parameter set.

This is a provisional obviousness-type double patenting rejection.

Allowable Subject Matter

Claims 24-43 and 45-47 would be allowable if rewritten the double patenting rejection set forth in this Office action, were overcome.

Claims 48, 49, 50-56, 83-99 are allowed. The allowability of claims 48-50 was addressed in the previous Office action filed 10/16/07.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding claims 24-43 and 45-47, the primary reason for allowance is the processor associating the sleep quality metric with the therapy parameter set and the memory receiving the sleep quality metric value and an indication of the therapy parameter set associated with the sleep quality metric value, in combination with all of the other limitations of the claims, which is not found in the prior art

Regarding claims 51-56, the primary reason for allowance is the implantable medical device associating each of the sleep quality metric values with at least one therapy parameter set and the external programming device including a display that receives the sleep quality metric values and indications of therapy parameter sets which the with which the sleep quality metric values are associated, in combination with all of the other limitations of the claims, which is not found in the prior art

Regarding claims 83-99, the primary reason for allowance is the combination of the processor determining a value of a metric that is indicative of sleep quality based on the identifications of when the patient is attempting to sleep and when the patient is asleep with the processor associating the sleep quality metric value with a therapy parameter set used by the medical device to deliver the therapy, in combination with all of the other limitations of the claims, which is not found in the prior art

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PATRICIA C. MALLARI whose telephone number is (571)272-4729. The examiner can normally be reached on Monday-Friday 10:00 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Examiner, Art Unit 3735